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10/551,456	09/30/2005	Nitin Bhalachandra Dharmadhikari	053180	3014

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WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP
1250 CONNECTICUT AVENUE, NW
SUITE 700
WASHINGTON, DC 20036

EXAMINER	
WELTER, RACHAEL E	
ART UNIT	PAPER NUMBER
1611	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,456	DHARMADHIKARI ET AL.	
	Examiner	Art Unit	
	RACHAEL E. WELTER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 1-23 are pending. Claims 19-23 are newly added claims.

Acknowledgements

Receipt of the amendment and remarks/arguments filed on 12/3/08 is acknowledged.

Specification

The objections to the specification are withdrawn in light of applicant's amendment.

Claim Objections

The objection of claims 1, 2, 8, and 12-14 is withdrawn in light of applicant's amendment.

Claim Rejections - 35 USC § 112

The rejection of claims 3 and 5 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's persuasive arguments and amendment.

Double Patenting

The rejection of claims 1-5, 7-8, and 11-15 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 11-15 of copending Application No. 11/946575 is withdrawn in light of applicant's amendment. The rejection of claims 1-5, 7-8, and 11-15 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25, 32, 38, and 39-41 of copending Application No. 10/572502 is withdrawn in light of applicant's amendment.

New Rejections

The following rejection constitutes new grounds for rejection necessitated by amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-11, 16-19, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Balaban et al (US Patent No. 5,209,746).

Balaban et al teach osmotically driven delivery capsules, which include a beneficial agent and a water absorptive osmotic engine in separate compartments to deliver the beneficial agent in a pulsatile manner through an orifice (abstract). The

capsule is surrounded by a wall surrounding the portion of the capsule interior which houses the osmotically active agent (column 3, lines 44-48). The wall is constructed of moisture-permeable and impermeable material (column 3, lines 44-50). The interior of the capsule comprises osmopolymers or hydrophilic polymers that swell upon contact with water, such as PVP, HPMC, etc (column 13, lines 5-32). The beneficial agents can be susceptible to decreased stability in the gastric environment, such as vitamins, targeted to the intestine for local action, such as betamethasone (corticosteroid), or an agent which has a side effect of causing bleeding or irritation of the gastric mucosa, such as naproxen or ibuprofen (column 13, lines 57-68; column 14, lines 1-45). In addition, the orifice is sealed with a band, but capable of being stretched by force of the primary piston to permit escape of the drug (column 9, lines 46-51). According to Balaban et al, the orifice is a small circular passage through the cylindrical side wall of the shell near the end wall (column 9, lines 37-41; Figures 5 and 7). Balaban et al teach that the closure of the orifice (band) is constructed to function in a manner similar to that of a check valve or relief value, opening only when the partition is in motion and returning to a closed position when the partition is immobilized by one of the stops (column 3, lines 13-16). Balaban et al teach that the release of drug is generally a short burst of drug delivery at a high rate followed by a longer delivery at a lower rate (column 5, lines 15-17).

Regarding (d) of claim 1, the examiner is interpreting the band to be the cover composition that does not completely cover the coat or Balaban's wall su,rrounding the capsule interior. The examiner refers to Figure 7 in Balaban et al, wherein reference

number 96 is the band. Since the band is sealing the orifice (column 9, lines 46-51) and only covering the orifice, it is not completely covering the coat or wall. Thus, Balaban et al teach the limitations of instant claims 1 and 22.

Regarding claims 6-7 and 16, wherein the composition used to cover the passageway releases the contents of the core at a predetermined time and location in the gastrointestinal tract after oral administration and the system provides delivery of the beneficial agent to a targeted site, Balaban et al teach that the delivery pattern may be varied by varying the spacing of the projections and the degree of force required to overcome them (column 5, lines 14-20). Furthermore, Balaban et al teach that structural and functional parameters of the capsules may be varied widely, and appropriate or optimal values and qualities for these parameters will vary with the particular application, such as the nature of the beneficial agent to be delivered, the type of environment into which the delivery is made, and the purpose of and desired protocol for the delivery, including the number, frequency, and intensity of the pulses (column 7, lines 55-61). Therefore, it is the position of the examiner that the limitations of claims 6-7 and 16 are expected properties of the drug delivery system since Balaban et al teach that the drug delivery system can be manipulated by varying the structural and functional parameters of the capsules, which would provide delivery at a predetermined time and location in the gastrointestinal tract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-20 and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al (US Patent No. 6,004,582) as evidenced by Amidon et al (US Patent No. 5,229,131).

Faour et al teach a multi-layered osmotic device that allows for the immediate delivery of a first active agent followed by a monitored, continuous, controlled, and/or retarded delivery of a second active agent which is the same or different as the first active agent (column 1, lines 7-10). The osmotic device comprises a compressed core comprising a first active agent, an osmotic agent, and optionally PVP, a semi-permeable membrane surrounding the core and having a preformed passageway therein (the membrane is permeable to a fluid in the environment of use and substantially impermeable to the first active agent), and an inert water soluble polymer coat comprising poly (vinylpyrrolidone)-(vinyl acetate) copolymer partially or substantially

completely surrounding the semi-permeable membrane and plugging the passageway in the wall (column 3, lines 49-65). The device also comprises an external coat comprising a second active agent for immediate release of the drug (column 3, lines 65-67). The active agent may be susceptible to decreased stability in the gastric environment, such as niacin, targeted to the intestine for local action, such as beclomethasone, or an agent which has a side effect of causing bleeding or irritation of the gastric mucosa, such as aspirin or naproxen (column 14, lines 29-30, 36; column 15, line 43).

Although Faour et al suggest the use of a water soluble polymer coat partially surrounding the semipermeable membrane, it not immediately envisaged and therefore the instant rejection is made under obviousness.

However, it would have been obvious to an artisan of ordinary skill at the time the invention was made to look at the guidance provided by Faour et al and only partially coat the semi-permeable membrane. One would have been motivated to do so to alter the release pattern of the dosage form, which is dependent on the needs of a particular patient population. A partial coating would result in a more immediate release of the core drug.

Regarding claims 10 and 17, which are directed to a dosage form exhibiting a pulsatile release, Faour's invention can have multiple separate drug layers, with multiple membranes and can release the beneficial agents in a concurrent manner. Thus, it is an expected property that Faour's system produces a pulsatile release (Figure 2; column 5, lines 58-64).

Regarding claims 12-15, Faour et al teach that the compositions may be designed to achieve pH-dependent and pH-independent delivery of the active agent (column 5, lines 58-61). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to create pH-dependent or pH-independent drug delivery systems with a reasonable expectation of success. One would have been motivated to do so since Faour et al suggest the creation of pH-dependent or pH-independent embodiments of the drug delivery system. Regarding the limitations of the targeted drug delivery being dependent on or independent of gastric emptying, Amidon et al disclose that pH dependent release systems affect release based on the variable pH in the small intestine and affect release time through gastric emptying; thus pH-dependent and pH-independent embodiments of Faour's invention would exhibit delays either dependent on or independent from gastric emptying time, respectively (column 5, lines 18-35 and 56-65; column 10, lines 62-68) as evidenced by Amidon et al.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection presented above necessitated by amendment.

Conclusion

Claims 1-23 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
March 14, 2009